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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/510,454
Filing Date: October 04, 2004
Appellant(s): KNIGHT CASTRO ET AL.

Anthony R. Kinney
Reg. No. 44,834
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/17/10 appealing from the Office action mailed 7/16/09.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1,2 and 5-18 are pending in the application. Claims 1,2,5 and 16-18 are rejected and claims 6-15 are withdrawn from consideration.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

the Manual and Operating Instructions, Nuclear Interface GmbH, including the Supplement FDG Synthesizers

6,172,207	Dumhaut et al.	1-2001
5,536,491	Asai et al.	7-1996
5,308,944	Stone-Elander et al.	5-1994

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,2,5 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Manual and Operating Instructions, Nuclear Interface GmbH, including the Supplement FDG Synthesizers, 11/21/01) in view of Dumhaut et al. (US

6,172,207B1) and further in view of Asai et al. (US 5,536,491) and evidenced by Stone-Elander et al. (5,308,944A).

The Manual and Operating Instructions discloses the method of improving the stability (avoiding decomposition) of a FDG solution. The method involves adjusting the pH of the FDG solution to 5.5 with a buffered product. It is important that the pH of the solution does not reach pH=6 because at this pH considerable degradation starts (p38). The Manual and Operating Instructions discloses heating the FDG with a buffer to a temperature of 135 degrees (4.3, p10, two sterilizing cycles) which encompasses the autoclave temperature of the instant invention as evidenced in the specification which teaches of an autoclave temperature of 134 degrees (spec, p4, line 1).

The Manual and Operating Instructions does not disclose that the FDG is labeled with 18F, that the buffering agent is citrate or that the solution is autoclaved.

Dumhaut et al. (US 6,172,207B1) discloses an 18F-FDG solution for NMR (example; column 3, line 28; column 6, line 33) where the pH adjustment and isotonicity to injectable standards of the final solution is performed by adding a buffer. The buffer may be a solution of citrate or sodium phosphate, tris or any other injectable buffer (column 5, lines 44-54). The disclosure states that the collected labeled compound is purified, filtered or sterilized (claim 22).

Asai et al. (US 5,536,491) discloses the sterilization of 19F-labeled MRI contrast agents via autoclave (example 30).

At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the citrate buffer of Dumhaut et al. for another known analogous

buffer disclosed in the Manual and Operating Instructions for the method of improving the stability of a FDG solution. It is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect, such as improving stability.

At the time of the invention it would have been obvious to one skilled in the art to use the known sterilization method of autoclaving a fluorine substituted contrast agent solution which is taught by Asai et al. with predictable results, such as providing a sterilized solution for the NMR/MRI imaging, as Dumhaut et al. teaches sterilization of 18F-FDG. The 18F isotope is stable against high temperature (as evidenced by Stone-Elander et al., see fig. 7; column 2, lines 22-25) and therefore will be capable of being successfully autoclaved/sterilized and maintain radiochemical purity after being autoclaved. FGD is also stable at a temperature of 135 degrees (where the specification teaches of an autoclave temperature of 134 degrees (spec, p4, line 1)) as evidenced by the Manual and Operating Instructions and therefore it would have been obvious to one ordinarily skilled in the art to autoclave 18F-FDG in a citrate buffer of Dumhaut et al. up to and including 135 degrees as The Manual and Operating Instructions teaches heating FDG up to 135 degrees.

(10) Response to Argument

Appellant asserts that there is no evidence of record to support a conclusion that a sufficient showing has been made that the reference The Manual and Operating Instructions was actually disseminated. Appellant asserts that numerous situations are

conceivable that explain the existence of the document, but that do not support the conclusion that the document was actually disseminated, including for example:

a.) the document is a revision and Nuclear Interface GmbH internally decided not to provide the manual to customers because, for instance (i) the design of the dispensing unit was changed before the document was disseminated, or (ii) the manual had incorrect information

b.) the document is a revision and sales of the dispensing unit were discontinued before it was disseminated

c.) the document is an internal draft or a draft of a revision that was not disseminated before being further revised

d.) the document was fabricated by the third party who submitted it to the EPO and was never produced by Nuclear Interface GmbH.

Appellant further asserts that the office has failed to establish that any of the above scenarios did not occur, that the document was actually disseminated or that the document was not subject to a confidentiality agreement.

The assertions stated above by the Appellant are the opinion of the Appellant, are based on hypothetical scenarios and are not based on any evidence. The Appellant disclosed the Manual and Operating Instructions, Nuclear Interface GmbH, including the Supplement FDG Synthesizers, 11/21/01) in the IDS filed 12/4/06 under CFR 1.56 and thus declared that the reference is considered material that is pertinent to patentability.

The Manual and Operating Instructions, Nuclear Interface GmbH, including the Supplement FDG Synthesizers is a manual for instrumentation which would be

disseminated to those who utilize or purchase the FDG Synthesizer. The Manual and Operating Instructions, Nuclear Interface GmbH, including the Supplement FDG Synthesizers, also provides contact information including a phone number, fax number, website and information email address which shows that the manual was distributed those skilled in the art that would ultimately require company contact information.

A REFERENCE IS A "PRINTED PUBLICATION" IF IT IS ACCESSIBLE TO THE PUBLIC and EXAMINER NEED NOT PROVE ANYONE ACTUALLY LOOKED AT THE DOCUMENT

A reference is proven to be a "printed publication" "upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it." In re Wyer, 655 F.2d 221, 210 USPQ 790 (CCPA 1981) (quoting I.C.E. Corp. v. Armco Steel Corp., 250 F. Supp. 738, 743, 148 USPQ 537, 540 (SDNY 1966)) ("We agree that printed publication' should be approached as a unitary concept. The traditional dichotomy between printed' and publication' is no longer valid. Given the state of technology in document duplication, data storage, and data retrieval systems, the probability of dissemination' of an item very often has little to do with whether or not it is printed' in the sense of that word when it was introduced into the patent statutes in 1836. In any event, interpretation of the words printed' and publication' to mean probability of dissemination' and public accessibility' respectively, now seems to render their use in the phrase printed publication' somewhat redundant.") In re Wyer, 655 F.2d at 226, 210 USPQ at 794. See MPEP § 2128 [R-5]

Appellant asserts that the Office has not established that dissemination of the document was not subject to a confidentiality agreement.

The Manual and Operating Instructions, Nuclear Interface GmbH, including the Supplement FDG Synthesizers is not labeled with a confidential or internal document stamp and thus is not subject to a confidentiality agreement.

Appellant asserts that if the autoclaving step of Asai et al. were substituted for the filtration step of Dumhaut et al., in order to achieve purification and sterilization, the buffer would be added after autoclaving of the solution and that one of ordinary skill in the art would have to find some motivation to rearrange the steps of Dumhaut et al.

The reference of Dumhaut et al. was not used to teach filtration but was used to teach of the use of a citrate buffered 18F-FDG solution for NMR.

The Manual and Operating Instructions was used to teach of the method of improving the stability (avoiding decomposition) of a FDG solution by adjusting the pH of the FDG solution to 5.5 with a buffered product prior to heating it to a temperature of 135 degrees (which encompasses the autoclave temperature of the instant invention as evidenced in the specification which teaches of an autoclave temperature of 134 degrees see specification, p4, line 1). Therefore, it would have been obvious to one of ordinary skilled in the art to substitute the buffer of the Manual and Operating Instructions for the equivalent citrate buffer of Dumhaut et al. as both are known to be used with FDG.

The reference of Asai et al. was used to teach that 19F-labeled MRI contrast agents are known to be sterilized by autoclave. Therefore, at the time of the invention it would

have been obvious to one ordinarily skilled in the art to autoclave a citrate buffered labeled FGD solution with predictable results, such as providing a sterilized solution for the NMR/MRI imaging as the Manual and Operating Instructions teaches of heating a buffered FDG solution to a temperature of 135 degrees (which encompasses the autoclave temperature of the instant invention as evidenced in the specification which teaches of an autoclave temperature of 134 degrees see specification, p4, line 1) and Asai et al. teaches that autoclaving is a known sterilization technique for fluorine substituted contrast agents.

Appellant asserts that Dumhaut et al. teaches away from use of an autoclaving step.

The reference of Dumhaut et al. was not used to teach of autoclaving but was used to teach of buffering an 18F-FDG solution for NMR with a citrate buffer. The Manual and Operating Instructions reference teaches of heating a buffered FDG solution to a temperature of 135 degrees and therefore it would have been obvious to substitute the citrate buffer of Dumhaut et al. for an analogous buffer, such as that of the Manual and Operating Instructions. It is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect, such as improving the stability.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

Conferees:

/Melissa Perreira/

Examiner, Art Unit 1618

Jon Epperson

/Jon D. Epperson/

Primary Examiner